

K101221



JUN - 2 2010

510(k) SUMMARY

General Information:

Date of Summary Preparation: May 28, 2010

Name and Address of Manufacturer: Pathway Medical Technologies, Inc.
10801 120th Ave NE
Kirkland, Washington 98033

Contact Person: Brian Cleary
Vice President of Clinical and Regulatory Affairs
Phone: 425-636-4079
Fax: 425-636-4001

Trade Name: Jetstream G3™ System

Common Name: Peripheral Atherectomy Catheter

Regulation Number: 21 CFR 870.4875

Regulation Name: Intraluminal Artery Stripper

Regulatory Class: Class II

Classification Panel: Cardiovascular

Product Code: MCW

Performance Standards: Performance Standards do not currently exist for these devices. None are established under Section 514.

Device Description: The Jetstream G3 System is an atherectomy catheter system designed with an expandable cutting tip for use in debulking and treating vascular disease in the peripheral vasculature. Separate lumens within the Catheter allow for continuous aspiration and infusion during device use. Excised tissue, thrombus, and fluid are aspirated from the peripheral treatment site through a port in the Catheter tip to a collection bag located on the Console. The distal portion of the Catheter also possesses infusion ports that provide continuous infusion of sterile saline during the atherectomy procedure.

The Jetstream G3 System consists of two primary components: (1) a Catheter with Control Pod and (2) a Console, which are packaged separately. Each of these system components is described generally as follows:

- **Jetstream G3 Catheter with Control Pod:** A sterile, single-use unit consisting of an electrically driven Catheter and Control Pod. The Catheter utilizes a differentially cutting tip and includes both aspiration and infusion capabilities. The Control Pod provides a user interface with keypad controls. The unit, its electrical connectors, tubing, and aspirant collection bag are packaged in a double-pouched tray.
- **PV Console:** A reusable compact Console, with two (2) peristaltic pumps for aspiration and infusion, power supply, system controller, keypad interface, and LED indicators for device operational status. The Console mounts on a standard I.V. stand and remains outside the sterile field during the procedure.

This 510(k) is for the same device most recently cleared under 510(k) K093456, but with the primary modifications intended to ensure any ingress of aspirated material into the guidewire lumen is minimized. In addition, the PATHWAY JETWIRE™ has been added as a compatible guidewire in the product labeling.

Indications for Use: The Jetstream System is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, iliac or renal vasculature.

Substantially Equivalent Devices: Pathway Medical cites the following devices as substantially equivalent predicate devices:

- Jetstream G3™ System (K100462)
- Jetstream G3™ System (K093456)
- Jetstream G3™ System (K092332)
- Jetstream G3™ L System (K093918)
- Jetstream G2™ System (K083837)
- Pathway PV™ Atherectomy System (K081328)

Testing Summary: To demonstrate substantial equivalence of the modified Jetstream G3 System to the predicate devices, the technological and performance characteristics were evaluated using *in vitro* testing as outlined below:

- System Reliability/Life
- Speed Drop – Flexibility
- Accessory Compatibility
- Infusion and Aspiration Flow Rates
- Catheter Trackability and Pushability
- Aspiration Efficiency and Crossing Time
- Thrombus Aspiration Challenge
- Guidewire and Device Wear
- Sterilant (EO) Residuals
- Control Pod Logic Verification
- Intended Use
- Pyrogenicity

The results from these tests:

- demonstrate that the technological and performance characteristics of the modified Jetstream G3 System are comparable to the predicate devices,
- support the safety and effectiveness of the modifications that are the subject of this 510(k), and
- ensure the modified device can perform in a manner equivalent to the listed predicate devices with the identical intended use.

Conclusion (Statement of Equivalence): The data and information presented within this submission (including *in vitro* testing) and the similarities between the modified and predicate devices support a determination of substantial equivalence, and therefore market clearance of the modified Jetstream G3 System through this 510(k) Premarket Notification.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

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Pathway Medical Technologies, Inc.
c/o Mr. Brian Cleary
Vice President of Clinical and Regulatory Affairs
10801 120th Ave NE
Kirkland, WA 98033

Re: K101221

Trade/Device Name: Jetstream G3 System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II (two)
Product Code: MCW

Dated: April 30, 2010

Received: May 3, 2010

Dear Mr. Cleary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

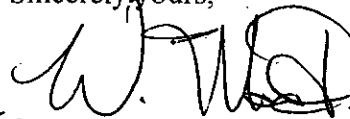
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K101221

Device Names: Jetstream G3™ System


Indications for Use:

The Jetstream System is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, iliac or renal vasculature.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

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